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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,676	02/21/2002	Samuel J. Epstein	12013/62001	4788
23838	7590	03/31/2006	EXAMINER	
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			RODRIGUEZ, CRIS LOIREN	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/078,676

Applicant(s)

EPSTEIN ET AL.

Examiner

Cris L. Rodriguez

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 12-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 21-25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Newly submitted and amended claims 15-20, and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: amended claim 15 contains subject matter not described for the elected species such as the catheter having a channel in fluid communication with a plug forming material and not described as originally filed in the specification, and claim 26 introduces new matter to the claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-20, and 26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10, and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are indefinite because it is not clear if the "a channel" is the same or in addition to the first channel cited in claim 8 or to the at least one channel in claim 21.

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- Claim 21 is unclear because "the channel" does not refer to the alternative (more than one channel). The examiner suggests the use of - the at least one channel- -.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 7-10, 14, 21-23, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Crank et al (US 6,616,626).

Crank discloses an injection catheter (figs. 10-12B) having an injection tube 282 with a piercing tip, a pressure apron (flange) 292. For the second injection tube, see figures 11A-11C).

6. Claims 1, 3, 6, 8, 10, 14, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al (US 6,045,565).

Ellis discloses an injection catheter (figs. 7-9) having an injection tube 190 with a piercing tip 127, and a pressure apron(hood) 163.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 6, 12, 13, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crank et al and Ellis et al in view of Wilk et al (US 5,758,663).

Crank and Ellis disclose the invention substantially as claimed except for the apron including an adhesive on its surface and the kind of adhesive material, and they are moot to the apron's material.

Wilk teaches that it is known to include a biocompatible adhesive on a cardiovascular device such as on a flange of a vascular bypass member in order to adhere a device to a patient's tissue. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Crank and Ellis's catheter by adding Wilk's adhesive on their apron (flange or hood), since Wilk suggests that it would adhere to elements together for a medical procedure, and it would improve the seal with the device and the tissue. Furthermore, the instant disclosure describes the material of the apron and the adhesive as merely preferable, and does not describe it as contributing any unexpected results to the catheter. As such, the materials are deemed matters of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in

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determining optimum results. See also *Sinclair & Carroll Co. v. Interchemical Corp.*, 325, U.S. 327, 65 USPQ 297 (1945).

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al in view of Goll (US 6,964,649) .

Ellis discloses the invention substantially as claimed except the apron having a truncated cone configuration, and made of the materials set forth in claim 6.

Goll teaches a catheter having a polymeric suction head 32 with a truncated cone configuration. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ellis's apron (hood) with Goll's configuration as an alternative configuration, since Goll teaches that it would also reduce tissue trauma and it would also increase conformity while the catheter touches the heart tissue. Furthermore, the selection of a polymeric material for the apron would have been an obvious design choice, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325, U.S. 327, 65 USPQ 297 (1945).

### ***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is 571-272-4964. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 29, 2006

  
Cris L. Rodriguez  
Primary Examiner  
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